

Remarks

Reconsideration and withdrawal of the rejections of the claims, in view of the amendments and remarks herein, is respectfully requested. Claims 5-6 and 26 are amended, and claim 28 is added. The amendments are intended to advance the application and are not intended to concede to the correctness of the Examiner's position or to prejudice the prosecution of the claims prior to amendment, which claims are present in a continuation of the above-identified application. Claims 5-6, 20-22 and 26-28 are pending.

Amended claims 5 and 6 are supported, for example, at page 14, line 25-page 15, line 4 and page 35, lines 4-7.

Amended claim 26 is supported at page 25, lines 20-26.

New claim 28 is supported by originally filed claims 5 and 6.

Applicant submitted an Information Disclosure Statement and a Form 1449 on April 18, 2001. Applicant respectfully requests that initialed copies of the Form 1449 be returned to Applicants' Representatives to indicate that the cited references have been considered by the Examiner. A copy of Form 1449 filed on April 18, 2001 is enclosed herewith for the Examiner's convenience.

The Examiner rejected claims 5-6, 22, and 26-27 under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for full length DNA repair proteins that bind to Mre11/Rad50, allegedly does not reasonably provide enablement for biological fragments thereof having DNA repair activity which bind to Mre11/Rad50. This rejection, as it may be maintained with respect to the pending claims, is respectfully traversed.

In particular, the Examiner asserts that it would require undue experimentation without a reasonable expectation of success to make and use fragments of p95. However, the specification describes assays to detect binding of p95 to double strand breaks in DNA and to Mre11/Rad50 (page 53, line 15-page 54, line 12, and page 74, line 25-page 75, line 12). Thus, the fact that the outcome of a screening program to identify fragments of p95 with selected activities, i.e., fragments which bind double strand breaks in DNA or form a complex with Mre11/Rad50, may be unpredictable is precisely why a program is carried out. The Examiner simply cannot reasonably contend that a program to locate biomolecules with target biological or

physical properties would not be carried out by the art because the results cannot be predicted in advance.

In fact, the Federal Circuit has explicitly recognized that the need, and methodologies required, to carry out extensive synthesis and screening programs to locate biomolecules with particular properties do not constitute undue experimentation. In re Wands, 8 U.S.P.Q.2d 1400, 1406-1407 (Fed. Cir. 1988), the Court stated:

The nature of monoclonal antibody technology is that it involves screening hybridomas to determine which ones secrete antibody with desired characteristics. Practitioners of this art are prepared to screen negative hybridomas in order to find one that makes the desired antibody.

Likewise, practitioners in the art related to the present application would be well-equipped to prepare and/or screen fragments of p95 to identify those which bind double strand breaks in DNA or form a complex with Mre11/Rad50. See also, Hybritech Inc. v. Monoclonal Antibodies Inc., 231 U.S.P.Q. 81, 84 (Fed. Cir. 1986) (evidence that screening methods used to identify characteristics [of monoclonal antibodies] were available to art convincing of enablement). Thus, the fact that a given claim may encompass a variety of molecules is not dispositive of the enablement issue, particularly in an art area in which the level of skill is very high and in which screening of large numbers of compounds has been standard practice for at least ten years (Ex parte Forman, 230 U.S.P.Q.2d 456 (Bd. App. 1986)).

The Examiner also rejected claims 26-27 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The amendment to claim 26 renders this rejection moot.

Accordingly, withdrawal of the § 112(1) rejections is respectfully requested.

Conclusion

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney ((612) 373-6959) to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743

Respectfully submitted,

JOHN H. PETRINI ET AL.

By their Representatives,

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. Box 2938
Minneapolis, MN 55402
(612) 373-6959

Date January 30, 2004 By Janet E. Embretson
Janet E. Embretson
Reg. No. 39,665

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 30th day of January, 2004.

Name

Dawn M. Poole

Signature

Dawn M. Poole